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Compulsory licensing: A nightmare awaiting pharma MNCs?

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Saxagliptin (Onglyza) is a drug used in treating type-2 diabetes. Initially, the molecule was discovered and developed by Bristol-Myers Squibb (BMS) and was later, in 2007, joined by AstraZeneca (AZ) to further develop and commercialize the product.

Saxagliptin's history

Between the co-developmental period 2007 through 2009, AZ solely bore the developmental costs, post which both the companies shared their spending for other additional costs incurred.

In the beginning of 2014, AZ acquired the entire BMS' diabetes business through a staggering $4 billion transaction.

The acquisition gave AZ complete ownership of all the intellectual properties (IP) and global rights for developing, manufacturing and commercializing BMS' diabetes drugs, which included Saxagliptin among others.

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Now it's Lee vs AZ

Recently, on June 25, 2015, Lee filed its application with the patent controller asking for the issuance of compulsory licensing for the manufacturing of Saxagliptin under the grounds that the reasonable requirements of the public with respect to the patented invention (Saxagliptin) have not been satisfied by AZ; the patented invention is not available to the public at a reasonably affordable price; and that the patented invention has not worked in the territory of India.

According to the Indian Patent Law, patents are granted so that the products are manufactured in India.

"Sec 83 of the Indian Patent Act clearly says that patents are granted to the owner neither just to enjoy the monopoly nor to import the product. Astra has been doing it even after the patent grant for the last seven or eight years," commented Mr Afzal Hasan, advocate, patent and trademark attorney and managing partner, Hasan and Singh.

"AstraZeneca has agreed to a certain extent that it has not been able to supply the population needs adequately. If we look at the number of people suffering from diabetes in India - their age and financial status - surely this is no more a rich-man's disease anymore. It (AZ) can sell the drug at much lower prices than what it is. AstraZeneca can manufacture the drug in India and bring down the prices rather than importing. We (Lee) have already told Astra that we have developed a process and are in a position to manufacture the drug in bulk at a lower price, and if interested, will supply it to Astra," explained Mr Hasan.

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AZ sells the drug for Rs 43/- and Lee, if granted compulsory license, is intending to sell it between Rs 20 to 25.

Gliptins market

India as a country is a home to 65.1 million diabetes patients. By 2035, this value will see a jump to 110 million, according to International Diabetes Federation (IDF) 2014.

Globally, diabetes caused at least $ 612 billion health expenditure in 2014. About 80 percent of the patients live in the middle- or low-income countries worldwide.

The total market for diabetes medication in India is valued at Rs 6,500 crore. IMS Health estimates that gliptins are valued at Rs 1,258 crore, which is 19 percent of the total market.

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The total number of patients on gliptin therapy in India is less than five percent out of the entire diabetic population, reflecting the high cost of gliptin products.

Tight lipped

In November 2014, Lee Pharma submitted all the documents to AZ showing its R&D capabilities, manufacturing facilities, infrastructure, and marketing abilities, to manufacture Saxagliptin.

However, there has been no communication from AZ's side so far.

Earlier in 2012, Indian patent office issued the first landmark compulsory license to generic maker Natco Pharma to manufacture German-based Bayer AG's Sorafenib (Nexavar), a cancer drug.

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A year later, in 2013, another compulsory licensing application was filed by Mumbai-based BDR Pharmaceutical International, for the manufacture of generic version of BMS' cancer drug Dasatinib (Sprycel). However, this time, the patent office rejected its application on the grounds that it has 'failed to make out a prima facie case for the making of an order under Section 87 of the Act'.

BDR was not available for comments when approached by *BioSpectrum*.

Now, what is the status of Lee's application filed at the controller's office? "There is no reason for the controller to reject our application," said Mr Hasan. "We have not received any form of communication from the controller as of now, but soon we will be, maybe in the next 6 months. Astra will have the opportunity to oppose this."

The controller has the power to judge whether this issue will need more time. "He has the right to reject the application if the manufacturing requirements and complex infrastructure needed to make the product is not available," Mr Hasan remarked.

Impact on Indian market

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As far as Indian market is concerned, if the compulsory licensing is granted to Lee, it will have a positive impact on Indian generic companies, believe experts.

"Most MNCs take Indian laws for granted. This will be a strong message to all the MNCs who have received Indian patents but do not follow the rules under which the patent has been granted," Mr Hasan pointed.

AZ has the patent in India and it was supposed to manufacture the drug in India than importing.

"In a way they are abusing the law. One has to follow the law and manufacture it within India. AZ cannot stop or deny the licensing to other companies to enjoy its monopoly by manufacturing overseas and importing it into India," added Mr Hasan.

Whether the drug is manufactured or imported, companies will have to supply as per the country's requirements and keep the pricing under control.

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Mr Hasan held that AZ cannot have such a monopoly that it fixes its own prices though it has a huge margin.

"If you are fixing the price for Indian customers, you have to keep in mind who the customers are and their income levels. You cannot sell the drugs equivalent to the prices in the US or Europe," he argued.

Do MNCs incur huge costs in their drug discovery R&D? Most of them respond with a big 'Yes'.

"I don't agree with that," defended Mr Hasan. "When a patent is granted, the company is able to recover the incurred R&D costs in a year or two. Companies cannot recover their entire R&D costs from Indian patients. This applies to Indian pharma companies as well. Majority of the Indian patients suffer from different diseases and are poorer with mere incomes and below poverty line."

Lee's application to obtain the license will be only within India. If needed, it will supply the API to other countries, it said.

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Now what for MNCs?

According to Mr Hasan, under the application, there is a provision for companies to oppose.

"It will have a negative impact on MNC pharma companies' commercial interest and they will oppose it. Thus, especially, the US has been attempting to remove section 3(D) of the Indian patent act. It is now the responsibility of the Indian government to first keep its country's population on top priority," ended Mr Hasan.

When *BioSpectrum* approached AZ's local and international offices for their next course of action, the emails went unanswered as on July 23, 2015. BMS too, did not respond.

Glenmark Pharma, on July 22, 2015, launched its diabetes drug, Teneligliptin, under the brand names Ziten and Zita Plus in Bangalore, which is used in treating type-2 diabetes, selling at the rate of Rs 19.90 per tablet.

Glenmark claimed that it is the only company in India to manufacture gliptins from API to formulation.

When asked will the compulsory licensing of Saxagliptin pose any threat to Teneligliptin, the company said, "We are not in a position to comment on this at the moment. But we will have to wait and watch."